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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,767	09/29/2003	Takashi Kitaoka	018961-065	7544
21839	7590	02/17/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			PRONE, CHRISTOPHER D	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/671,767	KITAOKA ET AL.
	Examiner	Art Unit
	Christopher D. Prone	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 January 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action, in view of the after final amendments, is persuasive and, therefore, the finality of that action is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application Publication Terumo (EP 0 795 304 A1).

In reference to claims 8 and 6 Terumo discloses the invention substantially as claimed being an indwelling stent formed in a substantially tubular shape comprising at least 2 annular units (4a-4f) arranged in an axial direction of said stent, each of said annular units comprises at least 4 annular elements referenced as elements (2a-2d) that are not arranged rectilinearly, an opening in a central portion thereof at reference numbers (17a-17e), adjacent portions of said annular elements are joined to each other through a joint (3a-3c), adjacent annular units being interconnected at their joints by at least one link (5a-5e) that is parallel to a axis but not continuous with another adjacent link, and a end portion with roughly semi-elliptic shape, said annular elements in each

said annular unit are arranged so that one of each adjacent pair of said annular elements is axially offset in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected end portion of said annular unit is in the state of penetrating into the adjacent annular unit, said joints in each said annular unit are substantially parallel to the stent axis shown in figures 6 and 7 of Terumo, wherein the annular elements are aligned substantially rectilinearly with respect to the axial direction of said stent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, and 9-19 are rejected under 35 U.S.C. 103 as being unpatentable over European Patent Application Publication Terumo (EP 0 795 304 A1) in view of Fischell (USPN 5,695,516).

In reference to claims 1-4, 7, 9, 10, 12, 14, 15, and 17 Terumo discloses the invention substantially as claimed being an indwelling stent formed in a substantially tubular shape comprising at least 2 annular units (4a-4f) arranged in an axial direction of said stent, each of said annular units comprises at least 4 annular elements referenced as elements (2a-2d) that are not arranged rectilinearly, an opening in a central portion

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thereof at reference numbers (17a-17e), adjacent portions of said annular elements are joined to each other through a joint (3a-3c), adjacent annular units being interconnected at their joints by at least one link (5a-5e) that is parallel to a axis but not continuous with another adjacent link, and a end portion with roughly semi-elliptic shape, said annular elements in each said annular unit are arranged so that one of each adjacent pair of said annular elements is axially offset in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected end portion of said annular unit is in the state of penetrating into the adjacent annular unit, and said joints in each said annular unit are substantially parallel to the stent axis shown in figures 8-12 of Terumo.

Note: In regard to claims 11 and 13, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113).

In reference to claims 11 and 13, which are product by process claims, the invention of Terumo meets all the structural requirements claimed. Therefore it is inherent that the invention of Terumo is produced with a predetermined outside diameter by use of a plastically deformable material-made pipe and then reduced in diameter by compressing from outside.

In reference to claim 18 Terumo discloses the invention substantially as claimed being an indwelling stent as disclosed above, wherein adjacent portions of said annular elements in each annular unit are joined to each other through a joint and the joints connecting the annular elements are substantially parallel to the stent axis.

In reference to claim 19 Terumo discloses the invention substantially as claimed being an indwelling stent wherein the link connecting first and second adjacent annular units is circumferentially shifted relative to the link connecting second and third adjacent annular units.

However, Terumo does not disclose that there are at least two links provided between each adjacent pair of annular units or the use of a radiopaque marker band.

Fischell teaches the use of a stent comprising multiple links connecting each annular unit for the purpose of maintaining the shape of the stent from the compressed shape to the expanded shape.

Fischell teaches the use of a stent comprising a radiopaque material marker described in column 3 on lines 22-29 in the same field of endeavor for the purpose of enhancing the visibility of the stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the stent structure of Terumo with the radiopaque markers and extra links as taught by Fischell in order to enhance the stents trackability and to enhance the stents ability to maintain its shape after expansion thereby giving the operator better visualization and control over the stent during implantation.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone  
Examiner  
Art Unit 3738

CDP



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
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